

**Title 2—DEPARTMENT OF
AGRICULTURE
Division 70—Plant Industries
Chapter 14—Missouri Cannabidiol Oil Rules**

EMERGENCY RULE

2 CSR 70-14.030 Supporting forms, documents, plans, and other information to be submitted with the applicant's application for a cultivation and production facility license.

PURPOSE: Outlines supporting information that must be submitted along with application for a cultivation and production facility license.

EMERGENCY STATEMENT: This emergency rule is necessary to serve a compelling governmental interest in that the Missouri General Assembly passed House Bill 2238 (SCS for HCS for HB 2238, 97th General Assembly, Second Regular Session (2014)), with an emergency clause providing that immediate action is necessary to provide individuals suffering from intractable epilepsy with access to anti-seizure medical treatment. This emergency rule is intended to implement the statutory framework provided in House Bill 2238 to allow the implementation of the non-traditional hemp oil treatment for epileptic seizures deemed necessary for the immediate preservation of the health, welfare, peace and safety of Missourians. The new law derived from House Bill 2238 that went into effect on July 14, 2014 requires the Missouri Department of Agriculture ("MDA") to promulgate rules for the licensure of non-profit cultivation and production facilities used to make hemp extract. The MDA has communicated with several potential licensees to discuss the regulatory structure for acquiring a facility license. The MDA must also maintain a list of growers of the cannabis plant used to make hemp extract for auditing purposes. The MDA rulemaking authority also allows for the inspection and sampling, independently or with law enforcement, of any hemp crop to determine if a crop contains a legally allowable tetrahydrocannabinol (THC) concentration in accordance with the federal Controlled Substance Act under 21 U.S.C. Section 801 et. seq. MDA must also promulgate rules for: application requirements for licensing; hemp monitoring systems; testing requirement to ensure that the hemp does not contain pesticides; manufacture, storage, and transportation of hemp extract; and license revocation and refusal protocols and civil penalties for any violations of these provisions. Anecdotal evidence suggests that a minimum of four hundred and fifty (450) Missourians may benefit from having hemp oil treatment for seizure activity resulting from intractable epilepsy. The Missouri Department of Agriculture promulgates this emergency rule to serve a compelling governmental interest to protect the public health, safety, and welfare because no person may legally obtain hemp oil treatment in Missouri until this rule is in effect. As a result MDA finds a compelling governmental interest which requires this emergency action. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri and United States Constitution**. MDA is convinced this emergency rule is fair to all interested parties under the circumstances. This emergency rule was filed October 8, 2014, becomes effective October 18, 2014 and expires April 15, 2015.

- 1) The applicant must submit to the director:
 - a) A signed affidavit, on a form provided by the Department, attesting to the applicant's acknowledgement and agreement to:
 - i) Follow inspection, testing, labeling, record keeping, and production requirements as established in section 261.265 RSMo and any regulations issued thereunder;

- ii) Pay the costs associated with sampling, labeling and testing hemp and hemp extract as established in section 261.265 RSMo and any regulations issued thereunder;
- iii) Submit fingerprints for and pay the associated costs of the Missouri State Highway Patrol and Federal Bureau of Investigation fingerprint-criminal background checks for the nonprofit entity's officers, board members, and all employees;
- iv) Certify that no board member, officer, or any employee has been convicted of any disqualifying offense/conviction.
- v) Notify local law enforcement officials that hemp will be grown within their jurisdiction, including the location of the cultivation and production facility;
- vi) Maintain a practical system to secure the facility from criminal activity. Said plan shall include, but is not limited to, lighting, physical barriers, video surveillance, and alarms;
- vii) Maintain a waste management plan that complies with the requirements of section 261.265 RSMo; and,
- viii) Maintain a hemp monitoring system as defined in section 261.265 RSMo.
- b) Official copies of the Missouri State Highway Patrol and Federal Bureau of Investigation fingerprint-criminal background checks for the nonprofit entity's officers, board members, and all employees.
- c) The nonprofit's operating by-laws.
- d) A copy of each license/registration/authorization document verifying current or previous licensure relating to the cultivation and production of hemp and hemp extract in another state or jurisdiction.
- e) A location map of the area surrounding the proposed cultivation and production facility. The map must clearly demonstrate that the proposed facility is not located within 2,000 feet of the property line of a pre-existing public or private preschool, elementary school, middle (junior high) school, high school, daycare facility, home day care, or an area zoned for residential use.
- f) A document explaining the applicant's ability to fulfill the requirements found in each measure of this section.
 - i) Proposed facility:
 - (1) Measure 1: The applicant shall provide evidence that the proposed facility is: suitable for effective and safe cultivation and production of hemp and hemp extract; sufficient in land, building size, power allocation, ventilation, lighting and interior layout; sufficient in area for storage, handling, processing, production, and distribution of hemp and hemp extract.
 - (2) Measure 2: The applicant shall provide evidence of the ability to expand the facility's production and distribution to meet qualified patient demand.
 - ii) Proposed staffing plan:
 - (1) Measure 3: The applicant shall provide a statement verifying staff experience with agricultural cultivation techniques and industry standards, including experience with the cultivation of agricultural or horticultural products, operating an agriculturally related business, or operating a horticultural business including, the submission of any academic degrees and certifications of all board members, officers and employees.
 - (2) Measure 4: The applicant shall provide a staffing plan that will ensure adequate experience and staffing for all business hours, safe hemp and hemp extract production, sanitation, security and theft prevention.

- (3) Measure 5: The applicant shall provide a plan and an employee handbook which includes a working guide to the understanding of the day-to-day administration of personnel policies and practices.
- iii) Cultivation and production plan:
 - (1) Measure 6: The applicant shall provide a cultivation and production plan that outlines their facility operations for producing hemp extract in compliance with the Act and any regulations issued thereunder.
 - (2) Measure 7: The applicant shall describe its plan to provide a continuous, uninterrupted supply of hemp extract.
 - (3) Measure 8: The applicant shall provide evidence relating to knowledge of cultivation and production methods to be used in the cultivation and production of hemp. The applicant shall list the hemp varieties to be cultivated and its experience with growing those varieties.
 - (4) Measure 9: The applicant shall describe the steps that will be taken to ensure the quality of the hemp, including the purity and consistency of the hemp extract.
- iv) Product safety and labeling plan:
 - (1) Measure 10: The applicant shall describe its plan for providing safe and accurate packaging and labeling of hemp extract.
 - (2) Measure 11: The applicant shall describe its plan for testing hemp to ensure it is free of contaminants, including but not limited to pesticides and microbiological organisms.
 - (3) Measure 12: The applicant shall describe its plan for establishing a recall of the applicant's hemp extract in the event that the hemp extract is shown by testing or other means to be potentially defective or have a reasonable probability that its use or exposure to will cause adverse health consequences. The plan must include the method of identification of the packaged hemp extract containers involved, notification to those whom the hemp extract was distributed to, and how the hemp extract will be disposed of if returned to or retrieved by the applicant.
- v) Security plan:
 - (1) Measure 13: The applicant shall provide evidence of its ability to prevent the theft or diversion of hemp and hemp extract and how the applicant will assist the Department, Missouri Highway Patrol and local law enforcement.
 - (2) Measure 14: The applicant shall describe its plan for record keeping, tracking, and monitoring production, distribution, inventory, quality control, security, and other policies and procedures in place to discourage unlawful activity.
 - (3) Measure 15: The applicant shall describe a plan for disposition of unusable, adulterated, misbranded, and recalled hemp and hemp extract and the applicant's coordination with Department, Missouri Highway Patrol, and local law enforcement for its disposal; and
- g) Any additional documentation the director deems necessary for the application process. The director may require a site inspection of the facility prior to approval.

AUTHORITY: Section 261.265, RSMo. Emergency rule filed October 8, 2014, effective October 18, 2014, expires April 15, 2015. A proposed rule covering this same material is published in this issue of the Missouri Register.